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PUBLIC HEALTH SERVICE

PHS INTERINSTITUTIONAL AGREEMENT

PHS-LEAD

This **Agreement** is entered into between the National Institutes of Health (“**NIH**”) or the Food and Drug Administration (“**FDA**”), hereinafter singly or collectively referred to as “**PHS**”, agencies of the United States Public Health Service within the Department of Health and Human Services (“**HHS**”) through the Office of Technology Transfer, **NIH**, having an address at 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804, U.S.A and _____, hereinafter referred to as the “**Institution**”, having an address at _____.

1. BACKGROUND

- 1.1 In the course of fundamental research programs at the **PHS** and by the **Institution**, _____ (hereinafter referred to as the “**Inventor(s)**”) made or reduced to practice certain inventions, which are included within the **Patent Rights**, as defined in Paragraph 2.1.
- 1.2 It is the mutual desire of the **Institution** and the **PHS** that their respective undivided interests in the **Patent Rights** be administered in a manner to ensure the rapid commercialization of the **Patent Rights** and to make their benefits widely available to the public. Therefore, the **Institution** is granting an exclusive license under the **Institution's** rights in the **Patent Rights** to the **PHS** under the conditions set forth herein.

2. DEFINITIONS

2.1 “**Patent Rights**” means:

- (a) Patent applications (including provisional patent applications and PCT patent applications) or patents as follows: U.S. Patent Application Serial No./U.S. Provisional Patent Application Serial No. _____/_____, _____, filed _____, entitled _____, and any patent application(s) claiming the benefit of priority thereof including all divisions and continuations of these applications, all patents issuing from such applications, divisions, and continuations, and any reissues, reexaminations, and extensions of all such patents to the extent that at least one **Inventor** from the **Institution** is an **Inventor** thereon;
- (b) to the extent that the following contain one or more claims directed to the invention or inventions disclosed in 2.1(a) and to the extent that at least one **Inventor** from the **Institution** is an **Inventor**:
 - (i) continuations-in-part of 2.1(a);
 - (ii) all divisions and continuations of these continuations-in-part;
 - (iii) all patents issuing from these continuations-in-part, divisions, and continuations;

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- (iv) priority patent application(s) of 2.1(a); and
 - (v) any reissues, reexaminations, and extensions of all these patents; and
 - (c) to the extent that the following contain one or more claims directed to the invention or inventions disclosed in 2.1(a) and to the extent that at least one **Inventor** from the **Institution** is an **Inventor**: all counterpart foreign and U.S. patent applications and patents to 2.1(a) and 2.1(b);and
 - (d) **Patent Rights** shall *not* include 2.1(b) or 2.1(c) to the extent that they contain one or more claims directed to new matter which is not the subject matter disclosed in 2.1(a).
- 2.2 “**Net Revenues**” means all consideration received by **PHS** from the licensing of the **Patent Rights** pursuant to this **Agreement** less (a) **Expenses** and then (b) fifteen percent (15%) of the remaining consideration for administrative overhead. In the event that a license is executed by **PHS** with a third party wherein the **Patent Rights** are licensed together with other technologies not falling under the definition of the **Patent Rights**, all consideration received by **PHS** from the licensing of the **Patent Rights** pursuant to this **Agreement** through the third-party executed license shall correspond to the **Patent Rights**’ percentage contribution to the total amount received for all licensed technologies as determined by **PHS**.
- 2.3 “**Expenses**” means all reasonable and actual out-of-pocket costs, excluding those reimbursed by a third party, incurred by **PHS** for the preparation, filing, prosecution, and licensing of United States and foreign patent applications, extraordinary expenses as provided in Paragraph 4.6, and the maintenance of the resulting patents or patent applications, exclusive of any salaries, administrative, or other indirect costs.

3. GRANT AND RESERVATION OF RIGHTS

- 3.1 The **Institution** hereby grants and **PHS** accepts, subject to the terms and conditions of this **Agreement**, an exclusive license including the right to sublicense, under the **Patent Rights** to make and have made, to use and have used, to sell and have sold, to offer to sell, and to import any tangible embodiment of the **Patent Rights** and to practice and have practiced any process(es) included within the **Patent Rights**.
- 3.2 The Government of the United States (hereinafter referred to as “**Government**”) shall have the irrevocable, royalty-free, paid-up right to practice and have practiced the **Patent Rights** throughout the world by or on behalf of the **Government** and on behalf of any foreign government or international organization pursuant to any existing or future treaty or agreement to which the **Government** is a signatory.

4. PATENT PROSECUTION AND PROTECTION

- 4.1 **PHS** shall file, prosecute, and maintain patent application(s) relating to the **Patent Rights** and shall promptly provide to the **Institution** all serial numbers and filing dates, together with copies of all the applications, including copies of all Patent Office actions, responses, and all other Patent Office communications. In addition, the **Institution** shall be granted Power of Attorney for all such patent applications. **PHS** shall consult with the **Institution**, when so requested, prior to communicating with any Patent Office with respect to the **Patent Rights**.

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- 4.2 **PHS** shall make an election with respect to foreign filing, upon consultation with the **Institution**. If any foreign patent applications are filed, **PHS** shall promptly provide to the **Institution** all serial numbers and filing dates. **PHS** also shall provide to the **Institution** copies of foreign patent applications and Patent Office actions. **PHS** shall consult with the **Institution**, when so requested, prior to communication with any Patent Office with respect to the **Patent Rights**.
- 4.3 **PHS** shall promptly record Assignments of domestic patent rights in the United States Patent and Trademark Office and shall promptly provide the **Institution** with a photocopy of each recorded Assignment(s) to the **Institution**.
- 4.4 Notwithstanding any other provision of this **Agreement**, **PHS** shall not abandon the prosecution of any patent application, including provisional patent applications (except for purposes of filing continuation application(s)) or the maintenance of any patent contemplated by this **Agreement**, without prior written notice to the **Institution**. Upon receiving the written notice, the **Institution** may, at its sole option and expense, take over the prosecution of any patent application, or the maintenance of any patent.
- 4.5 **PHS** shall promptly provide the **Institution** with copies of all issued patents under this **Agreement**.
- 4.6 In the event that **PHS** anticipates the possibility of any extraordinary expenditures arising from the preparation, filing, prosecution, licensing, or defense of any patent application or patent contemplated by this **Agreement**, including, without limitation, interferences, reexaminations, reissues and oppositions, **PHS** shall provide the **Institution** with all relevant information and these extraordinary expenditures shall be included as **Expenses** only upon written agreement of the **Institution**. **PHS** and the **Institution** shall agree on a mutually acceptable course of action prior to incurring these expenditures.

5. LICENSING

- 5.1 **PHS** shall diligently seek licensees for the commercial development of the **Patent Rights** and shall administer the **Patent Rights** for the mutual benefit of the parties and in the public interest.
- 5.2 **PHS** shall promptly provide the **Institution** with copies of all licenses and sublicenses granted for the **Patent Rights**.

6. ROYALTIES AND EXPENSES

- 6.1 **PHS** shall distribute **Net Revenues** to the **Institution** concurrently with distributions it makes under **PHS'** patent policy on the following basis: (a) _____ percent (X%) of the **Net Revenues** as a royalty to the **Institution** and (b) _____ percent (X%) of the **Net Revenues** as a royalty to **PHS**. All payments to the **Institution**, required under this **Agreement**, shall be in U.S. dollars and shall be made by check or bank draft drawn on a United States bank and made payable to _____. All payments shall be sent to the following address: _____.
- 6.2 **PHS** shall submit to the **Institution** annual statements of itemized **Expenses** and shall deduct the **Expenses** defined in Paragraph 2.2, except where the **Institution** has identified discrepancies in billing by **PHS**, in which case, deduction of the contested item(s) from **Net Revenues** shall be delayed pending resolution thereof. In no event shall **Institution** be obligated to bear any costs that exceed **Net Revenues** distributed to the **Institution** defined in Paragraph 6.1.

- 6.3 Each party shall be solely responsible for calculating and distributing to its respective **Inventor(s)** of the **Patent Rights** any share of **Net Revenues** in accordance with its respective patent policy, royalty policy, or Federal law during the term of this **Agreement**.

7. RECORDS AND REPORTS

- 7.1 **PHS** shall keep complete, true, and accurate accounts of all **Expenses** and of all **Net Revenues** received by it from each licensee of the **Patent Rights** and shall permit the **Institution** or the **Institution's** designated agent to examine its books and records in order to verify the payments due or owed under this **Agreement**. This examination shall not occur more than one (1) time in any single calendar year.
- 7.2 Upon request by the **Institution**, **PHS** shall submit to the **Institution** a report setting forth the status of all patent prosecution, commercial development, and licensing activity relating to the **Patent Rights** for the preceding calendar year.

8. PATENT INFRINGEMENT

- 8.1 In the event **PHS** or the **Institution**, including its licensees, shall learn of the substantial infringement of any patent subject to this **Agreement**, the party who learns of the infringement shall promptly notify the other party in writing and shall provide the other party with all available evidence of the infringement. **PHS** and its licensees, in cooperation with the **Institution**, shall use their best efforts to eliminate the infringement without litigation. If the efforts of the parties are not successful in eliminating the infringement within ninety (90) days after the infringing party has been formally notified of the infringement by **PHS**, **PHS** shall have the right, after consulting with the **Institution**, to commence suit on its own account. The **Institution** may commence its own suit after consultation with **PHS**.
- 8.2 **PHS** may permit its licensees to bring suit on their own account, and **PHS** shall retain the right to join any licensee's suit.
- 8.3 The **Institution** shall take no action to compel **PHS** either to initiate or to join in any suit for patent infringement. Should the **Government** be made a party to any such suit by motion or any other action of the **Institution**, the **Institution** shall reimburse the **Government** for any costs, expenses, or fees which the **Government** incurs as a result of the motion or other action, including all costs incurred by **PHS** in opposing any joinder action.
- 8.4 Legal action or suits to eliminate infringement or recover damages pursuant to Paragraph 8.1 shall be at the full expense of the party by whom suit is brought. All damages recovered thereby shall first be used to reimburse each party for its expenses related to the legal action or suit, and the remainder of the damages shall be considered **Net Revenues**.
- 8.5 Each party agrees to cooperate with the other in litigation proceedings. **PHS** may be represented, at its expense, by counsel of its choice in any suit.

9. GOVERNING LAWS, SETTLING DISPUTES

- 9.1 This **Agreement** shall be construed in accordance with U.S. Federal law, as interpreted and applied by the U.S. Federal courts in the District of Columbia. Federal law and regulations shall preempt any conflicting or inconsistent provisions in this **Agreement**. **Institution** agrees to be subject to the jurisdiction of U.S. courts.

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- 9.2 Any controversy or any disputed claim by either party against the other arising under or related to this **Agreement** shall be submitted jointly to the **Institution's** President or designee and to the Director of the **NIH** or designee for resolution. The **Institution** and **PHS** shall be free after written decisions are issued by those officials to pursue any and all administrative or judicial remedies which may be available.

10. **TERM AND TERMINATION**

- 10.1 This **Agreement** is effective when signed by all parties, unless the provisions of Paragraph 11.8 are not fulfilled, and shall extend to the expiration of the last to expire of the patents included within the **Patent Rights** unless otherwise terminated by operation of law or by acts of the parties in accordance with the terms of this **Agreement**.
- 10.2 **PHS** may terminate this **Agreement** upon at least sixty (60) days written notice to the **Institution**, but in any event, not less than sixty (60) days prior to the date on which any pending Patent Office actions need be taken to preserve patent rights for the benefit of the parties hereto.
- 10.3 The **Institution** may terminate this **Agreement** in whole or in part if:
- (a) **PHS** fails to make payments or periodic reports required by this **Agreement**;
 - (b) **PHS** has committed a substantial breach of a covenant or duty contained in this **Agreement**; or
 - (c) **PHS** and the **Institution** are involved in a dispute under this **Agreement** which cannot be resolved under the procedures specified in Paragraph 9.2.
- 10.4 If the **Agreement** is terminated under Paragraph 10.3, the **Institution** agrees to provide all affected licensees an opportunity to license the **Patent Rights** under such terms as may have been agreed to by **PHS**.

11. **GENERAL**

- 11.1 All **Agreement** notices required or permitted by this **Agreement** shall be given by prepaid, first class, registered or certified mail or by an express/overnight delivery service provided by a commercial carrier, properly addressed to the other party at the address designated on the following Signature Page, or to such other address as may be designated in writing by the other party. **Agreement** notices shall be considered timely if the notices are received on or before the established deadline date or sent on or before the deadline date as verifiable by U.S. Postal Service postmark or dated receipt from a commercial carrier. Parties should request a legibly dated U.S. Postal Service postmark or obtain a dated receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.
- 11.2 The **Agreement** shall not be construed to confer on any person any immunity from or defenses under the antitrust laws or from a charge of patent misuse, and the acquisition and use of rights pursuant to this **Agreement** shall not be immunized from the operation of state or Federal law by reason of the source of the grant.
- 11.3 It is agreed that no waiver by either party hereto of any breach or default of any of the covenants or agreements herein set forth shall be deemed a waiver as to any subsequent or similar breach or default.

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- 11.4 This **Agreement** is binding upon and shall inure to the benefit of the parties hereto, their successors or assigns, but this **Agreement** may not be assigned by either party without the prior written consent of the other party.
- 11.5 This **Agreement** confers no license or rights by implication, estoppel, or otherwise under any patent applications or patents of the **PHS** other than the **Patent Rights** regardless of whether such patents are dominant or subordinate to the **Patent Rights**.
- 11.6 Any modification to this **Agreement** must be in writing and agreed to by both parties.
- 11.7 It is understood and agreed by the **Institution** and **PHS** that this **Agreement** constitutes the entire agreement, both written and oral, between the parties, and that all prior agreements respecting the subject matter hereof, either written or oral, expressed or implied, shall be abrogated, canceled, and are null and void and of no effect.
- 11.8 The terms and conditions of this **Agreement** shall, at **PHS'** sole option, be considered by **PHS** to be withdrawn from **Institution's** consideration and the terms and conditions of this **Agreement**, and the **Agreement** itself to be null and void, unless this **Agreement** is executed by the **Institution** and a fully executed original is received by **PHS** within sixty (60) days from the date of **PHS** signature found at the Signature Page.

SIGNATURES BEGIN ON NEXT PAGE

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SIGNATURE PAGE

IN WITNESS WHEREOF, the parties hereto have executed this **Agreement** in duplicate originals by their respective duly authorized officers hereunto, on the day and year hereinafter written. Any communication or notice to be given shall be forwarded to the respective addresses listed below.

For **PHS**:

Steven M. Ferguson
Director, Division of Technology Development and Transfer
Office of Technology Transfer
National Institutes of Health

Date

Mailing Address for **Agreement** notices:

Chief, Monitoring & Enforcement Branch, DTD
Office of Technology Transfer
National Institutes of Health
6011 Executive Boulevard, Suite 325
Rockville, Maryland 20852-3804 U.S.A.

For the **Institution** (Upon information and belief, the undersigned expressly certifies or affirms that the contents of any statements of the **Institution** made or referred to in this **Agreement** are truthful and accurate.)
by:

Signature of Authorized Official

Date

Printed Name

Title

Official and Mailing Address for **Agreement** notices:

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Official and Mailing Address for Financial notices (**Licensee's** contact person for royalty payments)

Name

Title

Mailing Address:

Email Address: _____

Phone: _____

Fax: _____

Any false or misleading statements made, presented, or submitted to the **Government**, including any relevant omissions, under this **Agreement** and during the course of negotiation of this **Agreement** are subject to all applicable civil and criminal statutes including Federal statutes 31 U.S.C. §§3801-3812 (civil liability) and 18 U.S.C. §1001 (criminal liability including fine(s) or imprisonment).

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